

1615

228.1010

UNITED STATES PATENT AND TRADEMARK OFFICE

GOVERNMENT

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Re: Application of: REIN, Hubert et al.
Serial No.: 09/980,727
Filed: October 19, 2001
For: **METHOD FOR PRODUCING A WATER
INSOLUBLE AMORPHOUS
OR PARTIALLY AMORPHOUS CONTROLLED
RELEASE MATRIX**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

November 19, 2003

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 (18 pages) for consideration by the Examiner in connection with the examination of the above-identified patent application. Pursuant to 37 C.F.R. § 1.98(a), copies of the references listed on pages 1-18 of the Form PTO-1449 are enclosed. If it is determined that any of the listed references are not presently enclosed, the Examiner is requested to contact the undersigned so that a copy can be forwarded. It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record.

The Examiner's attention is respectfully directed to the following references, which are cited in the specification of the present application and are listed on the attached Form-PTO 1449:

- EP(A2) 0240906- corresponding U.S. patent listed as reference DD
- EP(A2) 0358105- corresponding U.S. patent listed as reference BG
- EP(A2) 0118240-listed as reference RH
- EP(A1) 0580860-listed as reference BN

The Examiner's attention is also respectfully directed to the following references, which were cited in the Preliminary Examination Report of the present application:

WO 92/15285-listed as reference RI

WO 98/10762-listed as reference RJ

U.S. Patent No. 4,612,009-listed as reference RD

Applicants respectfully advise the Examiner of the following U.S. Patents and co-pending U.S. Patent Applications which are commonly assigned to the owners of the instant application:

U.S. Application Serial No. 10/690,389, filed October 21, 2003, entitled, "Melt-Extruded Orally Administrable Opioid formulations", pending, which is a continuation of U.S. Application Serial No. 09/777,616, filed February 6, 2001, entitled, "Melt-Extruded Orally Administrable Opioid formulations", pending, which is a continuation application of U.S. Application Serial No. 09/360,056, filed July 23, 1999, entitled "Melt-Extruded Orally Administrable Opioid formulations", now U.S. Patent No. 6,261,599, issued July 17, 2001, which is a continuation application of U.S. Application Serial No. 08/833,948, filed April 10, 1997, now U.S. Patent No. 5,958,452, issued September 28, 1999, which is a continuation-in-part of PCT/US95/14745, filed November 3, 1995, which is a continuation-in-part of U.S. Application Serial No. 08/334,209, filed November 4, 1994, now U.S. Patent No. 5,965,161;

U.S. Application Serial No. 10/038,867, filed January 2, 2003, entitled, "Melt-Extrusion Multiparticulates", pending, which is a continuation application of 09/358,828, filed July 22, 1999, entitled, " Melt-Extrusion Multipartiulates", now U.S. Patent No. 6,335,033, issued January 1, 2002, which is a continuation application of U.S. Application Serial No. 08/334,209, filed November 4, 1994, entitled, "Extruded Multiparticulates", now U.S. Patent No. 5,965,161, issued October 12, 1999.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii), the Examiner's attention is directed to **Exhibit A**, attached herewith, which contains the following:

(i) the claims of pending applications serial nos. 10/690,389 and 09/777,616, which have the same specification as U.S. Patent No. 5,958,452, listed as reference RB on the attached Form PTO 1449.

(ii) the claims of pending application serial no. 10/038,867, which has the same specification as U.S. Patent No. 6,335,033, listed as reference RC on the attached Form PTO 1449.

The present Information Disclosure Statement is filed under 37 C.F.R. §1.97(c), after the mailing of a first Office Action on the merits. Accordingly, a check in the amount of **\$180.00** is enclosed. If it is determined that any additional fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

It is respectfully requested that the reference cited on the accompanying Form PTO-1449 be considered and made of record.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

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Reg. No. 41,240

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 228.1010		SERIAL NO.: 09/980,727						
LIST OF PRIOR ART CITED BY APPLICANT						APPLICANT(S): Hubert REIN, et al.								
(Use several sheets if necessary)						FILING DATE: October 19, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	4	1	3	2	7	5	3	01/02/79	Blichare et al.	264	25	11/03/67	
	AB	4	5	3	3	5	6	2	08/06/85	Ikegami et al.	427	3	04/19/84	
	AC	4	7	6	4	3	7	8	08/16/88	Keith et al.	424	435	02/10/86	
	AD	4	8	2	8	8	3	6	05/09/89	Elger et al.	424	419	05/19/87	
	AE	4	8	8	2	1	6	7	11/21/89	Jang	424	468	11/24/87	
	AF	4	8	8	0	8	3	0	11/14/89	Rhodes	424	470	02/09/87	
	AG	4	8	9	4	2	3	4	01/16/90	Sharma et al.	424	440	07/26/88	
	AH	4	9	9	4	2	2	7	02/19/91	Dietz et al.	264	328.16	02/03/89	
	AI	5	0	2	3	0	8	9	06/11/91	Sakamoto et al.	424	502	07/13/89	
	AJ	5	0	5	5	3	0	7	10/08/91	Tsuru et al.	424	693	12/28/89	
	AK	5	1	3	3	9	7	4	07/28/92	Paradissis et al.	424	480	01/24/90	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AL	WO	94	0	8	5	6	8	04/28/94	PCT	A61K	9/26	Abstract	
	AM	WO	94	2	3	6	9	8	10/27/94	PCT	A61K	9/14		
	AN	WO	93	2	4	1	1	0	12/09/93	PCT	A61K	9/20	Abstract	
	AO	WO	93	0	7	8	5	9	04/29/93	PCT	A61K	9/16		
	AP	0	4	8	1	6	0	0	04/22/92	EPO(A2)	A61L	15/28		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AQ	Nicolas Follonier ¹ , Eric Doelker and Ewart T. Cole, Evaluation of Hot-Melt Extrusion as a New Technique for the Production of Polymer-Based Pellets for Sustained Release Capsules containing high loadings of freely soluble drugs, Drug Development and Industrial Pharmacy, 20(8), 1323-1339 (1994)												
	AR	Nicolas Follonier ¹ , Eric Doelker ¹ and Ewart T. Cole ² , Hot-Melt Extruded Pellets for the Sustained Release of Highly Dosed Freely Soluble Drugs, Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 18(1991), pages 578-579												
	AS	Twin Screw Extrusion in the Production of Novel Dosage Forms, Pharmaceutical Manufacturing Review (June 1994)												
EXAMINER						DATE CONSIDERED								
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>														

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U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	GROUP: 1617		
	BA	5	2	7	3	7	5	8	12/28/93	Royce	424	465	04/13/92	
	BB	5	3	8	0	5	3	5	01/10/95	Geyer et al.	424	484	11/25/92	
	BC	5	2	0	2	1	2	8	04/13/93	Morella et al.	424	469	08/24/90	
	BD	Re.		3	3	0	9	3	10/17/89	Schiraldi et al.	424	676	11/16/88	
	BE	5	3	5	6	6	3	5	10/18/94	Raman et al.	424	484	07/13/93	
	BF	5	1	8	3	6	9	0	02/02/93	Carr et al.	427	213.31	06/25/90	
	BG	5	0	7	3	3	7	9	12/17/91	Klimesch et al.	424	467	08/25/89	
	BH	4	9	5	7	6	8	1	09/18/90	Klimesch et al.	264	211.23	04/03/89	
	BI	5	2	8	3	0	6	5	2/1/94	Doyon, et al.	424	467	3/23/92	
	BJ	4	8	0	6	3	3	7	2/21/89	Snipes, et al.	71	65	10/14/86	
	BK	5	2	9	0	5	6	0	3/1/94	Autant, et al.	424	438	6/21/91	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BL	2	0	8	2	5	7	3	05/24/93	Canada	A61K	047/38		
	BM	0	5	8	0	8	6	0	02/02/94	EPO (A1)	A61K	9/14		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	BN	Follonier, Nicolas, et al., "Hot-Melt Extruded Pellets For The Sustained Release Of Highly Dosed Freely Soluble Drugs", Capsule News, Vol. 1, No. 3, Edited by Roland Daumesnil, (June/July 1991)												
	BO	Frank W. Goodhart et al., Design and Use of a Laboratory Extruder for Pharmaceutical Granulations, Journal of Pharm. Scien., 62(1), p. 133-136 (January 1973).												
	BP	Publication, KEX, Twin Screw Compounding Extruder, (October 1989).												
EXAMINER						DATE CONSIDERED								
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

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						GROUP: 1615								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	CA	5	0	4	9	3	9	4	9/17/91	Howard, et al.	424	490	3/15/89	
	CB	4	8	6	1	5	9	8	8/29/89	Oshlack	424	468	7/18/86	
	CC	4	8	1	8	4	5	0	4/4/89	Hall, et al.	264	39	10/27/86	
	CD	4	7	2	0	3	8	4	1/19/88	DiLuccio, et al.	424	78	8/21/86	
	CE	4	3	7	4	0	8	2	2/15/83	Hochschild	264	129	8/18/91	
	CF	3	8	8	0	9	9	1	04/29/75	Yolles	424	22		
	CG	4	2	6	5	8	7	5	05/05/81	Byrne, et al.	424	19		
	CH	4	2	9	2	3	0	0	09/29/81	Byrne, et al.	424	19		
	CI	4	3	4	4	4	3	1	08/17/82	Yolles	128	260		
	CJ	4	3	4	6	7	0	9	08/31/82	Schmitt	128	260		
	CK	4	4	0	6	8	8	3	09/27/83	Byrne, et al.	424	80		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	CL	0	5	4	4	1	4	4	06/02/93	EPO (A1)	A61K	9/20	Abstract	
	CM	WO	93	0	7	8	5	9	04/29/93	PCT	A61K	9/16		
	CN	WO	93	1	8	7	5	3	9/30/93	PCT	A61K	9/16		
	CO	WO	92	1	8	1	0	6	10/29/92	Japan	A61K	9/14	Abstract	
	CP	9	3	0	0	0	6	3	01/07/93	WO (A1)	A61J	3/00		
	CQ	9	3	1	0	7	6	5	06/10/93	WO (A1)	A61K	9/22		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	CR	Abstract No. 2-223533 "Agent with Release-Controlled Matrix"												
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	DA	4	6	2	1	1	1	4	11/04/86	Watanabe	524	451		
	DB	4	6	4	9	0	4	2	03/10/87	Davis, et al.	424	438		
	DC	4	8	0	1	4	6	0	01/31/89	Goertz, et al.	424	465		
	DD	4	8	8	0	5	8	5	11/14/89	Klimesch, et al.	264	141		
	DE	4	9	7	0	0	7	5	11/13/90	Oshlack	424	451		
	DF	4	9	9	2	1	0	0	02/12/91	Koepff, et al.	106	125S		
	DG	5	1	0	2	6	6	8	04/07/92	Eichel, et al.	424	490		
	DH	5	3	5	0	5	8	4	09/27/94	McClelland, et al.	424	501		
	DI	5	4	5	6	9	2	3	10/10/95	Nakamichi, et al.	424	489		
	DJ	4	1	7	3	4	1	7	11/6/79	Kruder	366	89	6/20/78	
	DK	4	2	3	0	6	8	7	10/28/80	Sair et al.	424	22	5/30/78	
	DL	4	7	7	8	6	7	6	10/18/88	Yang et al.	424	79	12/20/85	
	DM	4	8	4	2	7	6	1	6/27/89	Rutherford	252	90	3/23/88	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	DN	0	2	3	9	9	8	3	11/21/91	EPO (B1)	A61J	3/06	Abstract	
	DO	0	2	7	5	8	3	4	07/27/88	EPO (A1)	A61K	9/20		
	DP	0	3	2	0	4	8	0	11/25/92	EPO (B1)	B01F	5/22		
	DQ	0	4	9	1	2	3	8	03/08/95	EPO (B1)	B30B	11/22		
	DR	2	2	0	7	3	5	5	01/23/91	Great Britain (B)	A61M	31/00		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	DS	Derwent Abstract DE 2553026 (1976)												
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EA	4	8	7	9	1	0	8	11/7/89	Yang et al.	424	440	10/14/88		
EB	4	8	8	2	1	5	1	11/21/89	Yang et al.	424	440	10/14/88		
EC	4	8	8	2	1	5	2	11/21/89	Yang et al.	424	440	10/14/88		
ED	4	8	8	2	1	5	3	11/21/89	Yang et al.	424	440	10/13/88		
EE	4	8	8	2	1	5	5	11/21/89	Yang et al.	424	440	10/14/88		
EF	4	8	8	2	1	5	6	11/21/89	Yang et al.	424	440	10/14/88		
EG	5	3	5	4	8	5	6	10/11/94	Kawashima et al.	536	127	05/23/91		
EH	4	8	8	2	1	5	7	11/21/89	Yang et al.	424	440	10/14/88		
EI	4	8	8	2	1	5	9	11/21/89	Yang et al.	424	440	10/14/88		
EJ	4	9	5	9	2	0	8	9/25/90	Chakrabarti et al.	424	78	10/28/88		
EK	5	0	3	5	5	0	9	7/30/91	Kruder	366	89	8/13/90		
FOREIGN PATENT DOCUMENTS														
	DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
	YES	NO												
EL	0	3	6	8	2	4	7	5/16/90	EP (A2)	A61K	9/26			
EM	0	3	7	5	0	6	3	6/27/90	EP (A1)	A61K	9/18			
EN	2	2	2	3	5	3	3	9/05/90	JP (A)	A61K	47/14	Abstract		
EO	2	2	2	3	5	1	3	9/5/90	JP (A)	A61K	9/10	Abstract		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
EP	Derwent Abstract of JP 62040277 (1987)													
EQ	Derwent Abstract of JP58109411 (1983)													
ER	Derwent Abstract EP 358 107 (1990)													
ES	Sekiguchi, et al., "Studies on Absorption of Eutectic Mixture.....", Chem. Pharm. Bull., Vol. 9 (1961), pp. 866-872													
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	FA	5	2	2	9	1	4	8	7/20/93	Copper	426	5	2/20/92	
	FB	5	2	4	0	4	0	0	8/31/93	Fujimoto et al.	425	310	7/27/92	
	FC	5	2	6	2	1	7	2	11/16/93	Sipos	424	490	6/19/92	
	FD	5	2	9	6	2	6	6	3/22/94	Kunugi et al.	427	213	2/19/91	
	FE	5	3	4	0	5	8	1	8/23/94	Tseng et al.	424	401	6/15/92	
	FF	5	4	7	6	5	2	8	12/19/95	Trimm et al.	71	21	12/20/93	
	FG	5	5	1	0	1	1	4	4/23/96	Borella et al.	424	452	5/2/94	
	FH	5	5	1	6	2	0	5	5/14/96	Oda et al.	366	75	1/12/95	
	FI	5	5	5	2	1	5	9	9/3/96	Mueller et al.	424	464	9/23/93	
	FJ	5	5	6	7	4	3	9	10/22/96	Myers et al.	424	486	11/4/94	
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	FL	2	2	7	3	5	8	4	1/2/76	FR	B 01 J	2/10	Abstract	
	FM	5	2	5	7	3	1	5	5/11/77	JP	A61K	9/22	Abstract	
	FN		6	6	5	0	1	0	10/14/93	EP (A1)	A61K	9/26		
	FO	1	5	0	4	5	5	3	3/22/78	GB	A61K	47/00		
	FP	8	9	7	6	0	9	1	6/18/92	AU (A)	A23L	001/09		
	FQ	9	4	2	2	4	3	1	10/13/94	WO	A61K	9/20		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	FR	A.R. Gennaro, "Particle Phenomena and Coarse Dispersions", Remington's Pharmaceutical Sciences, 17th Edition, 1985, p. 301												
	FS	J.L. Ford, "The Current Status of Solid Dispersions", Pharm. Acta Helv. 61, Nr. 3 (1986), pp. 69-88												
	FT	CA 74:67660 (1996) (1 page)												
EXAMINER										DATE CONSIDERED				
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	GA	3 7 1 4 3 5 0	01/30/73	Gough	424	203	
	GB	5 1 6 2 1 1 7	11/10/92	Stupak, et al.	424	475	
	GC	5 1 6 5 9 5 2	11/24/92	Solomon, et al.	427	2	
	GD	5 2 3 4 6 9 7	08/10/93	Sipos	424	490	
	GE	5 0 1 3 3 0 6	05/07/91	Solomon, et al.	604	265	
	GF	5 4 5 1 4 2 4	11/19/95	Solomon, et al.	427	2.1	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	GG	2 4 3 9 5 3 8	03/04/76	DE	A61K	9/22	Abstract
	GH	2 0 4 5 9 6	12/10/86	EP	A61K	9/14	Abstract
	GI	5 8 0 8 6 0	02/94	EP (A1)			
	GJ	0 5 2 9 3 9 6	03/03/93	EPO	A61K	9/20	abstract
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
GK	CA 101:60081 (1996) (1 page)						
GL	CA 113:98975 (1996) (1 page)						
GM	CA 113:218240 (1996) (1 page)						
GN	CA 114:30199 (1996) (1 page)						
GO	CA 112:75438 (1996) (1 page)						
GP	CA 115:177364 (1997) (1 page)						
GQ	R. Kinget, et al., "Preparation and Properties of Granulates Containing Solid Dispersions", Acta Phar. Tech., Vol. 31, No. 2, 1985, pp. 57-62						
EXAMINER		DATE CONSIDERED					
<p><small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small></p>							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 228.1010		SERIAL NO.: 09/980,727						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Hubert REIN, et al.								
						FILING DATE: October 19, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	HA	2	7	3	8	3	0	3	3/13/56	Blythe, et al.	167	82		
	HB	3	0	6	5	1	4	3	11/20/62	Christenson, et al.				
	HC	3	6	5	2	5	8	9	3/28/72	Flick, et al.	260	326.5M		
	HD	3	8	3	0	9	3	4	8/20/74	Flick, et al.	424	330		
	HE	3	8	4	5	7	7	0	11/5/74	Theeuwes, et al.	128	260		
	HF	3	9	5	0	5	0	8	4/13/76	Mony, et al.	424	19		
	HG	3	9	6	5	2	5	6	6/22/76	Leslie	424	22		
	HH	3	9	7	4	1	5	7	8/10/76	Shetty, et al.	260	247.2B		
	HI	4	0	1	3	7	8	4	3/22/77	Speiser	424	19		
	HJ	4	0	7	6	7	9	8	2/28/78	Casey et al.	424	419		
	HK	4	2	5	9	3	1	4	3/31/81	Lowey	424	19		
	HL	4	3	1	0	4	8	3	1/12/82	Dorfel, et al.	264	117		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	HM	9	1	1	9	4	8	4	12/26/91	PCT	A61K	9/16	Abstract	
	HN	9	1	1	9	4	8	5	12/26/91	PCT	A61K	9/16	Abstract	
	HO	9	2	0	1	4	4	6	2/6/92	PCT	A61K	9/50		
	HP	9	2	0	2	2	0	9	2/20/92	PCT	A61K	9/22	Abstract	
	HQ	9	2	0	5	7	7	4	4/16/92	PCT	A61K	9/18	Abstract	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	HR	M.J. Jozwiakowski et al., "Characterization of a Hot-Melt Fluid Bed Coating Process for Fine Granules", Pharm. Research, Vol. 7, No. 11, 1990, pp. 1119-24												
	HS	B. Evrard et al., "Melt Granulation With a New Laboratory High-Shear Mixer", Laboratoire de Pharmacie Galenique, Institut de Pharmacie												
	HT	M. Niskanen et al., "Pelletization in a Centrifugal Granulator, Part I: Effects of Binder-Solution Concentration", Pharm. Tech. Int'l., October 1990, pp. 22-38												
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													YES	NO
	IA	4	3	4	3	7	8	9	8/10/82	Kawata, et al.	424	461		
	IB	4	3	6	6	1	7	2	12/28/82	Lednicer	424	330		
	IC	4	3	8	0	5	3	4	4/19/83	Fukui, et al.	264	38		
	ID	4	3	8	9	3	9	3	6/21/83	Schor, et al.	424	19		
	IE	4	4	2	1	7	3	6	12/20/83	Walters, et al.	424	21		
	IF	4	4	8	3	8	4	7	11/20/84	Augart	424	22		
	IG	4	6	1	3	6	1	9	9/23/86	Sleigh et al.	514	546		
	IH	4	8	0	1	4	5	8	1/31/89	Hidaka, et al.	424	443		
	II	4	8	3	4	9	8	4	5/30/89	Goldie, et al.	424	488		
	IJ	4	8	4	4	9	0	7	7/4/89	Elger et al.	424	465		
	IK	4	8	4	4	9	0	9	7/4/89	Goldie et al.	424	480		
	IL	4	9	1	7	8	9	9	4/17/90	Geoghegan et al.	424	19		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	IM	9	2	0	6	6	7	9	4/30/92	PCT	A61K	9/16		
	IN	9	2	2	2	2	8	3	12/23/92	PCT	A61K	9/02		
	IO	9	3	0	0	0	7	6	1/7/93	PCT	A61K	9/51		
	IP	9	3	0	4	6	7	5	3/18/93	PCT	A61K	31/16		
	IQ	9	3	0	7	8	6	1	4/29/93	PCT	A61K	9/50		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	IR	L. Lachman et al., "The Theory and Practice of Industrial Pharmacy", p. 315, Lea & Febiger, Phi. 1976.												
	IS	FDA Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation, January 1994												
	IT	T. Schaefer et al., "Melt Pelletization in a High Shear Mixer I Effects of Process Variables and Binder", Acta Pharm. Nord. Vol. 4, No. 3, pp. 133-140, 1992.												
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													YES	NO
	JA	4	9	2	5	6	7	5	5/15/90	Giannini, et al.	424	78		
	JB	4	9	3	5	2	4	6	6/19/90	Ahrens	424	490		
	JC	4	9	6	7	4	8	6	11/6/90	Doelling	34	1		
	JD	4	9	7	0	0	7	5	11/13/90	Oshlack	424	451		
	JE	4	9	8	7	1	3	6	1/22/91	Kreek et al.	514			
	JF	4	9	9	0	3	4	1	2/5/91	Goldie et al.	424	484		
	JG	5	0	0	7	7	9	0	4/16/91	Shell	424	451		
	JH	5	0	2	6	5	6	0	6/25/91	Makino, et al.	424	494		
	JI	5	0	3	0	4	0	0	7/9/91	Danielson, et al.	264	101		
	JJ	5	1	2	6	1	4	5	6/30/92	Evenstad	424	465		
	JK	5	1	3	2	1	4	2	7/21/92	Jones, et al.	427	196		
	JL	5	1	6	7	9	6	4	12/1/92	Muhammed, et al.	424	482		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	JM	9	3	1	7	6	6	7	9/16/93	PCT	A61K	9/16		
	JN	9	4	0	3	1	6	0	2/17/94	PCT	A61K	9/32		
	JO	9	4	0	3	1	6	1	2/17/94	PCT	A61K	9/52		
	JP	9	4	0	5	2	6	2	3/17/94	PCT	A61K	9/16		
	JQ	9	4	2	3	7	0	0	10/27/94	PCT	A61K	9/16		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	JR	T. Schaefer et al., "Melt Pelletization in a High Shear Mixer II Power Consumption and Granule Growth", Acta Pharm. Nord. Vol. 4, No. 3, pp. 141-148, 1992												
	JS	T. Schaefer, et al., "Melt Granulation in a Laboratory Scale High Shear Mixer", Drug Dev. and Indust. Phar., Vol. 16, No. 8, pp. 1249-1277, 1990.												
	JT	McTaggart, C.M. et al., "The Evaluation of Formulation and Processing Conditions of a Melt Granulation Process", Int'L. J. Pharm. Vol. 19, No. 2, issued 1984, pp. 139-148												
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	KA	5	1	6	9	6	4	5	12/8/92	Shukla, et al.	424	499		
	KB	5	1	7	8	8	6	8	1/12/93	Malmqvist-Granlund et al.	424	490		
	KC	5	1	9	6	2	0	3	3/23/93	Boehm	424	490		
	KD	5	2	0	4	1	1	9	4/20/93	Shiobara, et al.	424	489		
	KE	5	2	6	6	3	3	1	11/30/93	Oshlack, et al.	424	468		
	KF	5	2	9	2	4	6	1	3/8/94	Juch et al.	264	37		
	KG	5	3	0	0	3	0	0	4/5/94	Egidio, et al.	424	456		
	KH	5	3	9	5	6	2	6	3/7/95	Kotwal, et al.	424	472		
	KI	5	4	0	3	5	9	3	4/4/95	Royce	424	489		
	KJ	5	4	4	3	8	4	6	8/22/95	Yoshioka et al.	424	498		
	KK	5	4	5	3	2	8	3	9/26/95	Münch et al.	424	489		
	KL	5	4	7	2	7	1	0	12/5/95	Klokkers-Bethke, et al.	424	468		
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		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	KM	9	5	1	4	4	6	0	6/1/95	PCT	A61K	9/14		
	KN	0	0	3	2	0	0	4	12/09/80	EP (A)	A61K	9/22		
	KO	0	0	4	3	2	5	4	5/30/84	EP (B1)	A61K	9/26		
	KP	0	0	6	8	4	5	0	1/10/90	EP (B1)	A61K	9/20		
	KQ	0	0	9	7	5	2	3	1/04/84	EP (A2)	A61K	9/26		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	KR	El-Shanawany, S., "Sustained Release of Nitrofurantion From Inert Wax Matrixes", J. Controlled Release, Vol. 26, No. 1, issued 1993, pp. 11-19												
	KS	P. Flanders, et al., "The Control of Drug Releases From Conventional Melt Granulation Matrices", Drug Dev. and Industrial Pharm., Vol. 13, No. 6, pp. 1001-22, 1987.												
	KT	Thomsen, L. Juul, "Matrix Pellets Prolonged Formulations Prepared by Melt Pelletization", Dept. of Pharm. Royal Danish School of Pharmacy, 1992												
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	LA	5	2	7	1	9	3	4	12/21/93	Goldberg, et al.	424	401	
FOREIGN PATENT DOCUMENTS													
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	LB	0	1	0	8	2	1	8	5/16/84	EP (A2)	A61K	9/22	
	LC	0	1	4	7	7	8	0	12/19/84	EP (A2)	A61K	9/32	
	LD	0	1	5	2	3	7	9	8/21/85	EP (A2)	A61K	9/50	Abstract
	LE	0	1	8	9	8	6	1	8/6/86	EP (A2)	A61K	47/00	
	LF	0	2	0	5	2	8	2	9/13/95	EP (B1)	A61K	9/22	
	LG	0	2	1	4	7	3	5	3/18/87	EP (A2)	A61K	9/22	
	LH	0	2	4	1	6	1	5	10/12/87	EP (B1)	A61K	9/22	
	LI	0	2	4	8	5	4	8	12/09/87	EP (A2)	A61K	9/22	
	LJ	0	2	4	9	3	4	7	12/16/87	EP (A2)	A61K	31/485	
	LK	0	2	4	9	3	4	7	12/16/87	EP (B1)	A61K	31/485	
	LL	0	2	5	1	4	5	9	1/07/88	EP (A2)	A61K	9/22	
	LM	0	2	5	3	1	0	4	1/20/88	EP (A1)	A61K	9/00	
	LN	0	2	5	4	9	7	8	2/3/88	EP (A1)	A61K	9/22	
	LO	0	2	5	6	1	2	7	2/24/88	EP (B1)	C12N	9/00	
	LP	0	2	6	7	7	0	2	5/18/88	EP (A2)	A61K	9/14	
	LQ	0	2	7	1	1	9	3	6/15/88	EP (A2)	A61K	31/485	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	LR	Thomsen, L. Juul, et al., "Prolonged Release Matrix Pellets Prepared by Melt Pelletization I. Process Variables", Drug Development and Industrial Pharmacy, Vol. 19, No. 15, pp. 1867-1887 (1993)											
	LS	Thomsen, L. Juul, et al., "Prolonged Release Matrix Pellets Prepared by Melt Pelletization II. Hydrophobic Substances as Melttable Binders", Drug Development and Industrial Pharmacy, Vol. 20, No. 7, pp. 1179-1197 (1994)											
	LT	Thomsen, L. Juul, "Utilizing melt pelletization technique for the preparation of prolonged release products", Pelletization, (material elaborated by assistant Prof. Lars Juul Thomsen, Dept. of Pharmaceutics, Royal Danish School of Pharmacy for the DIE course "Pelletization Technology", November 1992, 106 pages plus appendixes											
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	MA	5	4	7	8	5	7	7	12/26/95	Sackler et al.	424			
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		DOCUMENT NUMBER					DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
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	MB	0	2	9	5	2	1	2	12/14/88	EP (A2)	A61K	47/00		
	MC	0	3	2	7	2	9	5	8/9/89	EP (A2)	A61K	9/52		
	MD	0	3	5	1	5	8	0	1/24/90	EP (A2)	A61K	9/22		
	ME	0	3	6	1	6	8	0	4/4/90	EP (B1)	A61K	9/46		
	MF	0	3	6	1	9	1	0	4/4/90	EP (A1)	A61K	9/16		
	MG	0	3	7	7	5	1	7	7/11/90	EP (A2)	A61K	31/52		
	MH	0	3	7	7	5	1	8	1/90	EP (A2)	A61K	9/52		
	MI	0	4	1	5	6	9	3	3/6/91	EP (A1)	A61K	37/02		
	MJ	0	4	3	0	2	8	7	6/5/91	EP (B1)	A61K	9/54		
	MK	0	4	5	2	1	4	5	10/16/91	EP (A2)	A61K	9/14		
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	ML	Thomsen, L. Juul, "Prolonged Release Matrix Pellets Prepared by Melt Pelletization. Part IV: Drug Content, Drug Particle Size and Binder Composition", Pharmaceutical Technology Europa, pp. 19-22 (October 1994)												
	MM	N. Follonier et al., "Evaluation of Hot-Melt Extrusion as a New Technique for the Production of Polymer-Based Pellets for Sustained Release Capsules Containing High Loadings of Freely Soluble Drugs", Drug. Dev. and Industr. Pharm., Vol. 20, No. 8, pp. 1323-1339, (1994)												
	MN	Sustained Release Medications, pp. 50-53, Noyes Data Corp. (J.C. Johnson), 1980.												
	MO	M.A. Longer, "Sustained-Release Drug Deliver Systems", Remington's Pharm. Scie., 18th Edition, pp. 1676-1693, 1990.												
	MP	M. Zahirul I. Khan, "Recent Trends and Progress in Sustained or Controlled Oral Delivery of Some Water Soluble Drugs: Morphine Salts, Diltiazem and Captopril", Drug Devl. and Industr. Pharm., Vol. 21, No. 9, pp. 1037-1070, 1995.												
	MQ	J.P. Skelly, "Scael-up of Immediate Releae Oral Solid Dosage Forms, AAPS/FDA Workshop Committee, Pharmaceutical Technology, pp. 68-74, April 1995.												
	MR	SK Baveja et al., Int. J. Pharmaceutics, 41, (1988), pp. 55-62.												
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	NA	5	3	7	8	4	6	2	01/03/95	Boedecker, et al.	424	94.29	
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	NB	0	6	2	4	3	6	6	11/17/94	EPO (B1)	A61K	31/135	
	NC			5	7	2	2	4	5/7/86	Australia	A61K	47/00	
	ND	0	4	6	3	8	3	3	1/02/92	EP (A2)	A61K	9/26	
	NE	0	5	2	6	8	6	2	2/10/93	EP (A1)	A61K	9/20	
	NF	0	5	3	1	6	1	1	3/17/93	EP (A1)	A61K	9/02	
	NG	0	5	3	3	2	9	7	3/24/93	EP (A1)	A61K	9/46	
	NH	0	5	3	4	6	2	8	3/31/93	EP (A1)	A61K	31/485	
	NI	0	5	3	5	8	4	1	4/7/93	EP (A1)	A61K	31/485	
	JJ	0	5	4	6	6	7	6	6/16/93	EP (A1)	A61K	31/60	
	NK	0	5	8	2	3	8	0	2/9/94	EP (A1)	B01J	2/16	
	NL	0	5	9	5	3	1	1	5/4/94	EP (A1)	A61K	31/44	Abstract
	NM	0	6	0	9	9	6	1	8/10/94	EP (A1)	A61K	31/485	
	NN	0	6	2	4	3	6	6	11/17/94	EP (B1)	A61K	31/135	
	NO	0	6	3	6	3	7	0	2/1/95	EP (A1)	A61K	31/485	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	NP	Formulating for Controlled Release with METHOCEL® Premium Cellulose Ethers, The Dow Chemical Company, 1989.											
	NQ	M.S. Vazquez et al., Ddrug Dev. & Ind. Pharmacy, 18 (11 & 12), pp. 1355-1378 (1992).											
	NR	L W S Cheong et al., Pharm. Res. 9 (11), pp. 1510-1514 (1992).											
	NS	Hunt et al., Clin. Ther., Vol. 13, No. 4, pp. 482-488, 1990											
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	OA	5 7 0 0 4 1 0	12/23/97	Nakamichi et al	264	122		
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	OB	0 6 4 2 7 8 8	3/15/95	EP (A2)	A61K	31/135	Abstract	
	OC	0 9 9 7 3 9 9	7/07/65	GB				
	OD	1 4 0 5 0 8 8	9/03/75	GB	A61K	9/26		
	OE	1 5 1 3 1 6 6	6/7/78	GB	B29B	1/02		
	OF	2 0 3 0 8 6 1	4/16/80	UK (A)	A61J	3/08		
	OG	2 0 5 3 6 8 1	2/11/81	GB(B)	A61K	9/22		
	OH	2 1 1 1 3 8 6	7/06/83	GB (A)	A61K	9/20		
	OI	2 1 1 7 2 3 9	10/12/83	GB (A)	A61K	9/20		
	OJ	2 1 3 1 3 5 0	3/4/95	Canada (A1)	A61K	31/135		
	OK	2 1 9 6 8 4 8	5/11/88	GB (A)	A61K	9/22		
	OL	2 2 4 6 5 1 4	2/5/92	GB (A)	A61K	9/16		
	OM	2 2 8 1 2 0 4	3/1/95	GB (A)	A61K	9/16		
	ON	2 2 8 4 7 6 0	6/21/95	UK (A)	A61K	9/16		
	OO	2 6 4 2 4 2 0	8/03/90	FR (A1)	C07C	55/10	Abstract	
	OP	3 6 0 2 3 7 0	8/6/87	DE (A1)	A61K	45/06	Abstract	
	OQ	3 6 2 3 1 9 3	1/14/88	DE (A1)	A61K	31/205	Abstract	
	OR	4 3 2 9 7 9 4	3/9/95	DE (A1)	A61K	31/135	Abstract	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	OS	METHOCEL, Colorcon. Technical Information						
EXAMINER					DATE CONSIDERED			
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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 228.1010		SERIAL NO.: 09/980,727						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Hubert REIN, et al.								
						FILING DATE: October 19, 2001			GROUP: 1615					
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	PA	DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE				
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION				
										YES	NO			
	PB	0	3	3	8	3	8	3	10/25/89	EPO (B1)	A61K	9/54	Abstract	
	PC	2	0	8	2	5	7	3	5/24/93	CA	A61K	047/38		
	PD	2	1	5	0	3	0	4	12/1/95	CA (A1)	B01J	2/20		
	PE	2	2	8	1	2	0	4	3/1/95	GB (A)	A61K	9/16		
	PF	2	2	8	4	7	6	0	6/21/95	GB (A)	161K	9/16		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	PG	DA Alderman, Int. J. Pharm. Tech. and Prod. Mfr., 5(3), pp. 1-9, 1984.												
	PH	HE Huber et al., J. Pharm. Sci. 55 (9), Sept. 1966, pp. 974-976.												
	PI	Lin SY et al., Current Therapeutic Research 52 (3), pp. 486-492, Sept., 1992.												
	PJ	Aqualon Technical Information Bulletin, VC-585, 1991												
	PK	P. Colombo, Advanced Drug Delivery Reviews, 11 (1993), pp. 37-57.												
	PL	KV Ranga Rao et al., Int. J. Pharmaceutics, 48 (1988), pp. 1-13.												
	PM	JE Hogan, Drug Dev. & Ind. Pharmacy, 15 (6 & 7), p. 975-999, (1989)												
	PN	JL Ford et al., Int. J. Pharmaceutics, 24 (1985), pp. 327-338.												
	PO	PB Daly et al., Int. J. Pharmaceutics, 18 (1984), pp. 201-205.												
	PP	E.M.G. van Bommel, "Production and Evaluation of In Vitro Release Characteristics of Spherical Gradient Matrix Systems", Acta Phar., Technol. 3b (2), pp. 74-78, 1990.												
	PQ	Nicolas Follonier et al., "Various Ways of Modulating the Release of Diltiazem Hydrochloride from Hot-melt Extruded Sustained Release Pellets Prepared Using Polymeric Materials", Journal of Controlled Release, 36, pp. 243-250 (1995).												
	PR	Alan Royce et al., "Alternative Granulation Technique: Melt Granulation", Drug Development and Industrial Pharmacy, 22 (9 & 10), pp. 917-92 (1996).												
	PS	Derwent Abstract of EP 0208144, published 1-14-87												
EXAMINER							DATE CONSIDERED							
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U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
		4	2	8	0	9	7	1						
	QA	4	2	8	0	9	7	1	07/28/81	Wischniewski et al.	264	15		
	QB	5	1	4	7	5	9	3	09/15/92	Huttlin	264	500		
	QC	4	9	7	5	2	8	4	12/04/90	Stead et al.	424	497		
	QD	4	7	6	2	2	2	0	08/09/88	Lütke	198	519		
	QE													
	QF													
	QG													
	QH													
	QI													
	QJ													
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	QK	EP	02	0	8	1	4	4	1/14/87	EPO(A1)	A61K	9/16	Abstract	
	QL	EP	06	7	7	0	6	5	8/25/93	EPO(A1)	A61K	9/16		
	QM	9	1	0	4	0	1	5	4/4/91	WO	A61K	9/16		
	QN													
	QO													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	QP													
	QQ													
	QR													
EXAMINER									DATE CONSIDERED					
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	RA	6	2	6	1	5	9	9	7/17/2001	Oshlack et al.	424	457		
	RB	5	9	5	8	4	5	2	09/28/1999	Oshlack et al.	424	457		
	RC	6	3	3	5	0	3	3	01/01/2002	Oshlack et al.	424	457		
	RD	4	6	1	2	0	0	9	09/16/86	Drobnik et al.	604	891		
	RE													
	RF													
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	RG	0	5	7	4	8	9	4	12/22/93	EPO (A1)	A61K	31/575		
	RH	0	1	1	8	2	4	0	09/12/84	EPO(A2)	C 08 L	3/00		
	RI	9	2	1	5	2	8	5	09/17/92	WO	A61K	9/20		
	RJ	9	8	1	0	7	6	2	3/19/98	WO	A61K	31/435		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	RK	English translation of Japanese text of J.L. White, Twin Screw Extrusion, Technology and Principles, pages 14 and 37, 1981.												
	RL													
	RM													
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